

REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 3, 5, 6, 11-12, 14-16 and 18 are pending in this application. The element of claim 4 has been added to claim 1 and claim 4 has been cancelled. The element of claim 7 has been added to claim 6 and claim 7 has been cancelled. No new matter has been added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

“UNO” REJECTIONS

A. Claims 1, 3, 5 and 16 are rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Uno et al. (“Uno”) in view of Aiache et al. (“Aiche”), Nishihara et al. (U.S. Pat. Appl. Pub. 2002-0164379), Yasuda et al. (U.S. Patent 6,310,116) and Janda et al. (“Janda”).

Claim 1 has been amended to include the element of previously considered claim 4 which was not held to be obvious by the combination of Uno, Aiache, Nishihara, Yasuda and Janda. In addition, claims 3, 5 and 16 are each directly or indirectly dependent upon claim 1 and therefore, are also unobvious in light of claim 1 as amended.

B. Claims 1, 4, 14 and 15 are rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Uno et al. (“Uno”) in view of Aiache et al. (“Aiche”), Nishihara et al. (U.S. Pat. Appl. Pub. 2002-0164379), Yasuda et al. (U.S. Patent 6,310,116) and Janda et al. (“Janda”) as applied to claims 1, 3, 5 and 16 and further in view of Ohmura et al. (“Ohmura”).

For the purposes of advancing prosecution, the element of previously considered claim 4 was added to claim 1. However, the applicants do not believe that the combination of Uno, Aiache, Nishihara, Yasuda and Janda rendered claims 1, 3, 5 and 16 to be obvious as previously

considered (the applicants reserve the right to file a continuation application to further pursue the previous scope of the claim).

When making a determination of obviousness, the references, Uno, Aiache, Nishihara, Yasuda and Janda and the applicants' claimed invention must be considered as a whole. It is well known that "*it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.*" *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965)(emphasis added).

Moreover, the determination of whether the applicants' claimed invention is obvious is not a determination as to whether each individual element is obvious, but rather whether one of ordinary skill in the art would have found the simultaneous combination of the claimed elements to have been obvious.

While there is no limitation on the number of references which can be used to support an obviousness rejection, the very fact that five (5) references were needed to establish obviousness for a claim without an extraordinary number of elements is an indicia that the claimed invention would not have been obvious to one of ordinary skill in the art.

In addition, when considering the totality of the possible solutions represented by the combination of Uno, Aiache, Nishihara, Yasuda, Janda and Ohmura, one of ordinary skill in the art would not be confronted with a finite number of identifiable predictable solution or predictable results.

While these reasons are alone are sufficient to address the rejection of claims 1, 4, 14 and 15 over Uno, Aiache, Nishihara, Yasuda, Janda and Ohmura, in order to preserve the issue for Appeal, the applicants address the use of Ohmura.

It is noted that Uno does not teach or suggest inclusion of compounds such as MAPTAC in view of the effects achieved by the monomer having a nitrogen atom in its side chain such as (meth)acrylamide (i.e. the drug delivery ophthalmic lens of the present invention has excellent strength with less change in size as well as having high inclusion and sustainable release of a drug (see page 5, fourth paragraph of applicants' specification)).

In contrast, Ohmura does not show high inclusion or sustainable release of the cationic group-containing which is unsurprising as it is generally directed to modifying the surface of

polymer materials and contains no teaching regarding ophthalmic lenses. As such, one of ordinary skill in the art would not have found the particular element of a monomer having a nitrogen atom in its side chain being (meth)acrylamide to be an obvious element to be selected as Ohmura (or any other of the cited references) lends no direction to such a selection or even to a selection of this element to the exclusion of any other possible combination of teaching represented by the combination of Uno, Aiache, Nishihara, Yasuda, Janda and Ohmura.

Therefore, claims 1, 4, 14 and 15 are also unobvious over Uno, Aiache, Nishihara, Yasuda, Janda and Ohmura because there was no teaching to select the claimed element of a monomer having a nitrogen atom in its side chain being (meth)acrylamide, no finite number of solutions when considering the references as a whole and no predictability of results.

C. Claims 1, 16 and 18 are rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Uno et al. ("Uno") in view of Aiache et al. ("Aiache"), Nishihara et al. (U.S. Pat. Appl. Pub. 2002-0164379), Yasuda et al. (U.S. Patent 6,310,116) and Janda et al. ("Janda") as applied to claims 1, 3, 5 and 16 and further in view of Kamashita et al. ("Kamashita").

Claim 1 has been amended to include the element of previously considered claim 4 which was not held to be obvious by the combination of Uno, Aiache, Nishihara, Yasuda, Janda and Kamashita. In addition, claims 16 and 18 are each directly or indirectly dependent upon claim 1 and therefore, are also unobvious in light of claim 1 as amended.

"SULC REJECTIONS"

D. Claims 6 and 7 are rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Sulc et al. ("Sulc") in view of Aiache et al. ("Aiache"). The applicants request reconsideration of the rejections for the following reasons. The applicants request reconsideration of this rejection for the following reasons.

As the Office Action acknowledges that Sulc never teaches the claimed ratio of the invention (the closest embodiment is 90.7% of Example 1 of Sulc), the arguments previously presented in the amendment after final rejection are still applicable here, i.e. there was no direction to suggest that the anionic/cationic parameter was to be optimized; the only direction came from the necessity of the Office Action to account for this difference which would not have

existed to one of ordinary skill in the art who does not have the applicants' claims before them as does the Examiner.

Furthermore, Sulc refers to cationic-anionic pairs which are employed in the polymerization of a *balanced charge polymer* of their invention is made up of substantially equimolar amounts of an ethylenically unsaturated cationic monomer and an ethylenically unsaturated anionic monomer (see col. 2, lines 51-59) in order to provide a hydrophilic contact lens exhibiting a significantly reduced tendency to accumulate proteinaceous materials, etc. upon its surface (see col. 2, lines 41-47).

Based on the disclosure of Sulc, at best one of ordinary skill would adjust the molar ratio of the anionic monomer to the cationic monomer to 1:1 in order to achieve the desired lack of debris retention on the lens surface. This is further borne out by the previous example of Sulc highlighted in the previous Office Action, i.e. Example 17 which had a ratio of 109%. Taking Examples 1 and 17 as representative teachings, one of ordinary skill in the art would be directed to anionic/cationic ratios which deviate less than 10% from 100% with the preferred direction being 100% (i.e. a 1:1 ratio), i.e. 90% is not encompassed nor is there any reason to experiment in that direction. Therefore, the claimed molar ratio of the anionic monomer to the cationic monomer is not obvious to one of ordinary skill over Sulc.

Aiache is only relied upon for a generic teaching of drug delivery from an ophthalmic lens and the inclusion of an anionic group containing drug and does not remedy the deficiencies of the Sulc reference.

Therefore, claims 6 and 7 are unobvious over Sulc and Aiache as the combination of references fail to teach or suggest all elements of the applicants' claimed invention.

E. **Claims 6, 11 and 12** are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sulc et al. ("Sulc") in view of Aiache et al. ("Aiache") as applied to claims 6 and 7 and in further view of Lee et al. (Material Science and Engineering C, 2002, 20:161-166), Atkinson et al. (EP 0032443 - "Atkinson") and Kato et al. ("Kato"). The applicants request reconsideration of the rejections for the following reasons.

As claims 11 and 12 are directly or indirectly dependent upon claim 6, the arguments presented above with respect to Sulc in view of Aiache would also be applicable to claims 11

and 12. The reason for modifying Sulc is even further removed for the element of claim 11 - "the copolymer contains the anionic monomer in a ratio of 40 to 80 mol. % to the cationic monomer." As noted above, Sulc is directed to "a polymer of essentially *balanced charge*" (see Background of the Invention (col. 1, lines 6-8 and Description of Preferred Embodiments (col. 2, lines 49-52))

The applicants' previous response with respect to the inclusion of water-soluble azulene (claim 12) and the use of Kato was never adequately addressed as there was no factual basis for the opinions offered with regard to the teachings of Kato.

As with all cited references, the Kato reference must be considered as a whole with the teachings of Sulc and Aiache. One of ordinary skill in the art reading the Kato reference would clearly see that it refers to the formation of *liposomes for the treatment of dry eye*. The liposomes are unrelated to the contact lenses of the applicant's claimed invention or Sulc and Aiache nor does Kato contain the polymers which are related to either the applicants' claimed invention or that of Sulc and Aiache.

Moreover, Kato's reference to sodium azulene sulfonate is within a list of *non-essential ingredients* cited by Kato (see col. 2, lines 6-33) and furthermore, these non-essential components are used with the liposome in the context of treating dry eye, i.e. for the rapid release of the non-essential component whereas Sulc does not teach a release rate for active substances at all.

In contrast, the active ingredient within the applicants' claimed drug delivery ophthalmic lens achieves a much slower and controlled release rate of the active ingredient (see Example 7).

This rejection is essentially the same as the Sulc, Aiache and Kato combination first presented in the final rejection with the exception of the addition of Lee and Atkinson.

However, as Lee and Atkinson does not remedy the deficiencies of the combination of Sulc, Aiache and Kato, claims 6, 11 and 12 are unobvious over the cited references for this reason alone.

In order to keep the issue alive for Appeal, the applicants note that Lee and Atkinson at best suggest the optimization of conditions in Sulc which would destroy the inventive characteristics of Sulc's product, i.e. having a polymer of essentially balanced charge. It is well known that "[if the] proposed modification would render the prior art invention being modified

unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

For any of the above reasons, claims 6, 11 and 12 are unobvious over the combination of Sulc, Aiache, Lee, Atkinson and Kato.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: /Howard C. Lee/
Marilyn M. Brogan Howard C. Lee
Reg. No. 31,223 Reg. No. 48,104
Telephone: (212) 588-0800
Facsimile: (212) 588-0500